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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/538,837 | 06/13/2005 | Chikamasa Yamashita | 04676.0183 | 5653 |
| 22852 | 7590 | 10/22/2008 | | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | | |
| | | | EXAMINER | |
| | | | ALSTRUM ACEVEDO, JAMES HENRY | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-----------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/538,837 | YAMASHITA ET AL. | |
| | Examiner | Art Unit | |
| | JAMES H. ALSTRUM ACEVEDO | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
 - 4a) Of the above claim(s) 1-5 and 10-22 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 6-9 is/are rejected.
- 7) Claim(s) 6 and 8 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 June 2008 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/21/06.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) Notice of Informal Patent Application
- 6) Other: ____.

DETAILED ACTION

Claims 1-22 are pending. It is noted that claims 14-22 do not currently recite statutory subject matter. Claims 14-22 have been omitted from the below restriction requirement, because these claims do not recite statutory subject matter, and upon amendment to recite statutory subject matter, will be appended to an existing group or added to a new group as deemed appropriate. Claims 1-5 and 10-22 are withdrawn from consideration. Claims 6-9 are under consideration in the instant office action.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, drawn to a freeze-dried composition.

Group II, claim(s) 3-5, drawn to a method of manufacturing a dry powdered preparation.

Group III, claim(s) 6-9, drawn to a dry powder inhalation system*.

Group IV, claim(s) 10-13, drawn to a transpulmonary administration method.

* It is unclear whether “a dry powder inhalation system” is intended by Applicants to refer to an apparatus or a method due to the phrase “using a combination of” and for the purposes of this restriction this group has been interpreted as referring to an apparatus.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

technical features for the following reasons: the special technical feature of Group I is the freeze-dried composition characterized by the properties recited in claim 1, whereas the special technical feature of Group III, for example, is the device comprising a needle part having an air jet flow path. Thus, the different groups do not share the same special technical feature and there is no unity of invention present.

During a telephone conversation with Mr. Charles E. VanHorn on September 30, 2008 a provisional election was made without traverse to prosecute the invention of Group III, claims 6-9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-5 and 10-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The abstract of the disclosure is objected to because it utilizes legal phraseology, such as "novel" and "said". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. **The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 6 and 8 are objected to because of the following informalities: (1) the word "liquid" in line 4 of claim 6 should be located in front of the word "composition" not after the word "composition"; and (2) the term "high-molecular-weight" in claim 8 should be written as three separate words that are not connected via hyphens (i.e. high molecular weight). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the phrase "using a combination of" causes confusion as to whether the claimed "dry powder inhalation system" is an apparatus or is intended as a method. Appropriate clarification and correction are required.

Claim 6 is also indefinite because it is unclear what is meant by "cake-like" and how one would ascertain at which point a non-powder solid ceased to be "cake-like". Appropriate clarification and correction are required.

Claim 6 is indefinite, because it is unclear whether the item in parentheses on line 9 of said claim is intended as an example of a mean particle diameter. It is noted that a mean geometric diameter is not equivalent to a mass median aerodynamic diameter (MMAD), because MMAD is equivalent to the mean geometric diameter multiplied by the square root of the density.

Claim 6 recites the limitation "the powder form freeze-dried composition" in line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 is also indefinite, because the term "fine particle fraction" (FPF) is not defined in the specification to refer to particles having a diameter less than or equal to some maximum value. The art defines fine particle fraction variably, thus, the generic reference to a "fine

particle fraction" of at least 10% is indefinite, because the ordinary skilled artisan would be unable to ascertain which particle diameter necessarily defined the upper threshold of the claimed fraction. *See* U.S. Patent Nos. (1) 6,461,591 (FPF is defined as stages 2-8 of an Andersson Impactor, which corresponds to a particle size of ~ 0.43 microns to 9 microns) (col. 11, lines 54-59; Table 1, col. 12, lines 1-20); (2) 6,394,085 indicates that FPF is normally smaller than 6 microns (col. 7, line 12); and (3) 6,284,282 defines FPF as having a aerodynamic mass median diameter of less than 6.8 microns.

The term "high-molecular weight" in claim 8 is a relative term which renders the claim indefinite. The term "high-molecular-weight" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "drug" has been rendered indefinite by the term "high-molecular-weight".

The remaining claims are rejected as depending from a rejected claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Yamashita et al. (US 2003/0101995).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Applicants claim a dry powder inhalation system comprising (i) a vessel housing a freeze-dried composition having (a) a non-powder cake-like form, (b) a disintegration index of 0.05 or more, and (c) a property of becoming fine particles having a mean aerodynamic diameter of 10 microns or less or a fine particle fraction of 10% or more upon receiving an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec and (ii) a device comprising (1) a member capable of applying said air impact to the freeze-dried composition in said vessel, and (2) a member for discharging said [non]-powder form freeze-dried composition that has been made into fine particles.

Yamashita discloses the same dry powder inhalation system as claimed by Applicants, in Yamashita's Figure 1 and exemplified, for example, in Examples 1-13 [0436]-[0439] (see also Table 1 in [0437]). The disintegration indices of the non-powder solids contained in the vessel of the dry powder inhalation system of Figure 1 and exemplified in Examples 1-13 are all greater than 0.05 (in fact, higher than 0.1). The non-powder solids utilized in the examples were characterized as being cake-like [0436] and were prepared by freeze-drying liquid compositions. Application of an air jet with an air velocity of 35 m/sec and an air flow rate of 40 ml/sec resulted in aerosolized fine particles characterized by a MMAD of much less than 10 microns (all had a MMAD between about 1.5 and 3.8 microns) and a fine particle fraction of less than ~ 5 microns of approximately 100% (See Figures 14-18). The interferon-alpha in Examples 1-13 reads on "high molecular weight" active agent.

Yamashita also discloses that a more preferred disintegration index is 0.05 or more [0154]. The components of the dry powder inhalation system of Figure 1 are described in [0071]-[0072] and include a vessel, stopper, freeze-dried composition, air jet flow path, discharge flow path, needle part, inhalation port, air intake member, tubular safety cover, air pressure-feeding means, bellow body, intake valve, intake port, discharge valve, discharge port, connecting port. The functioning of Yamashita's invented dry powder inhalation system is described in [0127]-[0129].

Claims 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Yamashita et al. (US 2003/0101995)

The applied reference has a common assignee (i.e. Otsuka Pharmaceuticals) and some common inventors (i.e. Yamashita, Akagi, and Fukunaga) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicants' claims have been described above. The disclosures of Yamashita have been set forth above. Applicants' claims are anticipated by Yamashita as set forth above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 75, 83, 111-114 of allowed copending application No. 10/170,339 (allowed ‘339)¹ in view of Yamashita et al. (US 2003/0101995).

Independent claim 6 of the instant application claims a dry powder inhalation system² comprising (i) a vessel housing a freeze-dried composition having (a) a non-powder cake-like form, (b) a disintegration index of 0.05 or more, and (c) a property of becoming fine particles having a mean aerodynamic diameter of 10 microns or less or a fine particle fraction of 10% or more upon receiving an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec and (ii) a device comprising (1) a member capable of applying said air impact to the freeze-dried composition in said vessel, and (2) a member for discharging said [non]-powder form freeze-dried composition that has been made into fine particles. Independent claim

1 of allowed '339 claims a dry powder inhalation system comprising (1) a vessel housing a freeze-dried composition that contains an active ingredient, wherein the composition has (a) a non-powder form, (b) a disintegration index of 0.015 or more, and (c) a property of becoming fine particle having a mean particle diameter of 10 microns or less or a fine particle fraction of 10% or more upon receipt of an air impact having an air speed of at least 1 m/sec and an air flow rate of at least 17 ml/sec and (2) a device comprising (i) a path to apply said air impact (i.e. a member capable of applying said air impact) and (ii) a path to discharge the freeze dried composition (i.e. a member capable of discharging said [non]-powder freeze-dried composition. Independent claim 75 of allowed '339 claims a similar dry powder inhalation system as independent claim 1 of allowed '339, which additionally comprises (a) a source of pressurized air, (b) an inhalation port, (c) a 1st needle part comprising a first flow path, (d) a 2nd needle part comprising a 2nd flow path. The difference between the cit^{ed} claims of the instant application and allowed '339 is that the claims of allowed '339 do not recite the phrase "using a combination of", that the vessel and device are used in combination at the time of inhalation (claim 7 of the instant application), specify that the active ingredient is a "high molecular weight" drug (claim 8 of the instant application), or that said device comprises a stopper that seals the vessel and is pierced by a needle or needles (claim 9 of the instant application). These deficiencies are cured in part by the language of the claims of allowed '339 and in part by the teachings of Yamashita. The claims of allowed '339 clearly articulate that the claimed dry powder inhalation system is intended for transpulmonary administration and that said system comprises a vessel and a device. Thus, it would be obvious per this language that one would use both components together at the

¹ Copending application No. 10/170,339 was allowed on July 9, 2008 and Applicants paid the issue fee on October

time of inhalation administration. Regarding the stopper and molecular weight of the stopper, Yamashita teaches that the system of allowed '339 contemplates using both low molecular weight and high molecular weight drugs ([0312]-[0313]), as well as a stopper as described in claim 9 of the instant application [0236]-[0238]). Thus, the claims of the instant application represent an obvious modification of the claims of allowed '339 in view of the teachings of Yamashita.

Claims 6-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 8-9 of copending Application No. 12/202,220 (copending '220). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application represent an obvious modification of the claims of copending '220, which is substantially overlapping in scope with the claims of copending '220. Thus, the claims are considered to be mutually obvious as explained below. Independent claim 6 of the instant application has been described *supra*. Independent claim 1 of copending '220 is identical with claim 6 of the instant application, except for the recited disintegration index range of copending '220, which has a lower minimum value encompassing the disintegration index range recited in the claims of the instant application. The claims of the instant application represent a species of the genus claimed in copending '220. A species anticipates a genus, and anticipation is the epitome of obviousness. It is the Examiner's position that the similarity in the magnitude of the minimum disintegration index range of the instant application and copending '220 represents

merely a difference in degree, which is insufficient to render the claims of the instant application patentably distinct from the claims of copending '220.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 6-9 are rejected. Claims 6 and 8 are objected. Claims 1-5 and 10-22 are withdrawn from consideration. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
Patent Examiner, Art Unit 1616
Technology Center 1600

² This claim and claims dependent therefrom have been treated as claiming an apparatus and not a method.